K011590

MAR 2 0 2002

510(K) SUMMARY
(as required by 807.92 9(c))

Submitter of 510(K):

Regulatory & Marketing Service, Inc. (RMS)
3234 Ella Lane
New Port Ritchey, Florida 34655

Phone: 813-645-2855
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Contact Person: Art Ward

Date of Summary:

Trade Name: Resorb-X Resorbable Plating System

Classification Name: Plate, Fixation, Bone, Non-Spinal, Non-Metallic

Predicate Device:

K955729, K960988, K971870, K974309, K992158 – W. Lorenz Lactosorb® Trauma Plating System
K972913 – Macropore Protective Sheet
K974554 – Synthes Resorbable Fixation System
K982139 – BioSorbFX, Bioabsorbable Fixation System
K982531 – Howemedica Fixation System
K993061 – Stryker Leibinger System

Device Description/ Comparison:

The KLS-Martin Resorb-X resorbable plating system consists of all necessary Instrumentation to employ three diameters of screws with associated plates and meshes. The screws are Poly (D, L)-Lactid-Acid (PDLLA) and are available in diameters 1.6mm, 2.1mm and 2.4mm. The plates and meshes are the same material and vary in shape, size and thickness, and may be used with any of the above diameter screws to fixate.

The screws and plates are provided pre-sterilized by gamma irradiation and are not intended to be resterilized by the end user.

The screws are not intended to be used without a plate.

The screws require a pilot hole and this pilot hole must be tapped.

The plates are not intended to be used for fracture compression.

The Resorb-X system is not intended for use in the mandible.

Intended Use:

The KLS-Martin Resorb-X System is intended for fractures of the craniofacial skeleton including, but not limited to, comminuted fractures of the naso-ethomoidal and infraorbital areas, comminuted fractures of the frontal sinus wall, and midface fractures; and reconstructive procedures of the midface or craniofacial skeleton.

The KLS-Martin Resorb-X System is NOT intended for use in the mandible or full load-bearing situations, nor in areas of active infection or for patients with conditions including blood supply limitations, insufficient quantity or quality of bone, or latent infections.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2002

KLS-Martin L. P.
C/O Mr. Arthur Ward
Regulatory and Marketing Services
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K011590
Trade/Device Name: Resorb-X Resorbable Plating System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: December 21, 2001
Received: December 26, 2001

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011590

Device Name:

Resorb-X Resorbable Plating System

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

(Optional Format 1-2-96)

Susan Runyon

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011590